K042916

DEC 2 9 2004

510(k) SUMMARY

Itamar's Watch PAT 100S

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Itamar Medical Ltd.
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Contact Person: Koby Sheffy, Ph.D.

Date Prepared: September 27, 2004

Name of Device and Name/Address of Sponsor

Watch-PAT 100S

Itamar Medical Ltd.
2 Ha'eshel Street, P.O. Box 3579
Caesarea 38900 Israel

Common or Usual Name

Ventilatory Effort Recorder

Classification Name

Breathing Frequency Monitor (21 C.F.R. § 868.2375)

Predicate Devices

Itamar's Watch PAT 100 ("WP100")
Oxford BioSignal's BioSleep ("BioSleep")

Intended Use / Indications for Use

The Watch-PAT100S (WP100S) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP100S is a diagnostic aid for the detection of sleep related breathing disorders and rapid eye movement ("REM") sleep stages. The WP100S generates a peripheral arterial tonometry ("PAT") respiratory disturbance index ("PRDI") and PAT REM sleep stage identification ("PREM"). The WP100S's PREM provides supplemental information to its PRDI. The WP100S's PREM is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The WP100S is not indicated for children less than 17 years old. The WP100S is contraindicated for patients with latex allergy.

Technological Characteristics

The WP100S uses peripheral arterial tonometry to generate apnea indices ("PRDIs") and identify REM sleep stages ("PREMs"). The device's primary components include a cleared oximeter and actigraph, an associated computer analysis program, a battery and charger, and a carrying case.

Performance Data

Clinical data demonstrates that the device is as safe and effective as manual scoring of polysomnography ("PSG") and automated scoring of the BioSleep in detection REM sleep stages. Clinical data also demonstrated that the WP100S is at least as safe and effective as the Watch-PAT100 in detecting sleep apnea.

Substantial Equivalence

The WP100S is substantially equivalent to manual scoring of PSG data and a combination of the WP100 and the BioSleep. The WP100S has the same intended use as the WP100, very similar indications as a combination of the WP100 and the BioSleep, and the same hardware and principles of operation as the WP100. The minor technological differences between the WP100S and its predicate devices, namely the WP100S's software modifications, raise no new issues of safety or effectiveness. Clinical data demonstrate that the WP100S is as safe and effective as its predicates. Thus, the WP100S is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2004

Itamar Medical Limited
C/O Mr. Jonathan S. Kahn
Regulatory Counsel
Hogan & Hartson, L.L.P
555 Thirteenth Street, NW
Washington, DC 20004

Re: K042916
Trade/Device Name: Watch-PAT 100S
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 21, 2004
Received: October 21, 2004

Dear Mr. Kahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Watch-PAT 100S

Indications for Use:

The Watch-PAT 100S ("WP100S") device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP100S is a diagnostic aid for the detection of sleep related breathing disorders and rapid eye movement ("REM") sleep stages. The WP100S generates a peripheral arterial tonometry ("PAT") respiratory disturbance index ("PRDI") and PAT REM sleep stage identification ("PREM"). The WP100S's PREM provides supplemental information to its PRDI. The WP100S's PREM is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

The WP100S is not indicated for children less than 17 years old. The WP100S is contraindicated for patients with latex allergy.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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